Symposium Presenters

Industry Spotlight Presenters

Esther Bleicher
General Counsel
Hello Heart

Esther Bleicher joined Hello Heart in 2022 as General Counsel and oversees their legal functions. Esther has over 15 years of experience in life science and healthcare, having worked at FDA for nearly a decade and later held positions at Ohana Biosciences (Head of Regulatory and Legal Affairs), Valo Health (VP, Chief Counsel, Therapeutics & Technology, Head of Privacy), and Syntropy (Digital Ethics Advisor). Esther earned her J.D. from Harvard Law School, Master of Public Health from Harvard T.H. Chan School of Public Health, and Bachelor's in Philosophy from Dartmouth College.

Robert Blood
Executive Vice President, Chief Legal Officer and General Counsel
Candela Medical

Robert Blood joined Candela in 2018 as Executive Vice President, Chief Legal Officer and General Counsel. Robert has over 20 years of legal experience and is a leader in legal, public reporting, intellectual property and compliance functions at innovative life science companies. Prior to joining Candela, Robert held positions at Merck (Senior Counsel), EMD Serono (Associate General Counsel), AMAG Pharmaceuticals (Vice President of Legal Affairs, Deputy General Counsel & Chief Compliance Officer), and Voyager Therapeutics (Vice President of Legal Affairs).

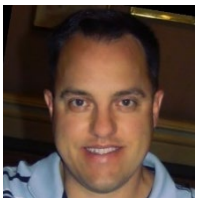
Shanya Dingle
Head of Government and Internal Investigations
Kenvue

Shanya Dingle is a litigator whose practice focuses on white collar defense and investigations. Shanya has extensive experience representing major companies in civil and criminal

investigations by the Department of Justice and other federal agencies. In particular, Shanya has expertise in handling health care matters involving fraud and abuse, the False Claims Act, and the Anti-Kickback Statute. She has advised pharmaceutical and technology companies on regulatory and enforcement risks related to digital health and electronic health records. In addition, Shanya has investigatory and courtroom experience from her tenure as a federal prosecutor.

Mary Lynne Kupchella
VP, Deputy General Counsel
Foundation Medicine

Mary Lynne Kupchella joined Foundation Medicine in 2020, bringing 15 years of legal and life sciences experience to the organization. Mary Lynne was most recently Director of Legal at Illumina, and has held roles at Sandoz Inc. (Senior Corporate Counsel) and Pfizer (Associate Director). She earned her J.D. from William & Mary Law School and Bachelor's in Biology from Franklin & Marshall.



Paul Laurino
Head of Legal, Connected Care
Philips

Paul Laurino has been with Philips for 18 years and has ascended to his current role as Head of Legal, Connected Care. Prior to his time at Philips, Paul held positions as an attorney at Ropes and Gray and Palmer & Dodge LLP. He holds a J.D. from Columbia Law School and a Bachelor's in Government from Harvard University.

Jean Liu
Associate General Counsel
Microsoft

Jean Liu is Associate General Counsel for Microsoft. She has more than 27 years of experience leading compliance, privacy programs and most previously served as Chief Legal, Privacy, and Compliance Officer at Nuance Communications. She holds a J.D. from the Loyola University of Chicago School of Law and a B.S. degree in Psychology from the University of Illinois Urbana-Champaign. She is a member of the Massachusetts, Illinois, and Federal Bar Associations.

Anil Ranganath
Senior Vice President, General Counsel and Corporate Secretary, Life Sciences & Medical Devices
TransMedics, Inc.

Anil Ranganath joined TransMedics in 2023, bringing over 15 years of experience providing counsel in the life sciences and biotechnology tools industries. Throughout his career, he served multiple roles of increasing scope and responsibility at Waters Corporation. Most recently, Anil served as Vice President, Deputy General Counsel for Waters, managing legal affairs, and serving as a trusted advisor on Waters' strategic, tactical, and operational plans. Earlier in his career, he served as an attorney at Brown Rudnick LLP, representing life sciences and biotechnology companies on corporate and intellectual property matters. Anil holds a J.D. from Suffolk University Law School and a bachelor's degree in Computer Science from Worcester Polytechnic Institute.

Rob Spadafora
Head of Legal
Philips North America

Rob Spadafora has been with Philips for 14 years and has been Head of Legal for North America for nearly six. Rob has over 15 years' experience representing medtech, pharmaceutical and biotechnology companies. His practice ranges from corporate, M&A and regulatory law to intellectual property and employment law. Prior to his time at Philips, he was the Vice President of Legal Affairs at Oscient Pharmaceuticals, and Legal and Intellectual Property counsel at Genome Therapeutics Corporation.

Larry Weiss
Former Chief Legal Officer
Butterfly Network and Analog Devices

Larry Weiss has nearly 30 years of experience as an attorney, including 20 years in the medical device industry with Medtronic, Covidien, and Tyco Healthcare. Most recently, he served as the Chief Legal Officer for Butterfly Network and led their Legal and Compliance and Quality and Regulatory teams on all legal and compliance matters, quality assurance and regulatory affairs. Prior to Butterfly Network, Larry served as Chief Legal Officer for Emulate, a venture capital backed life sciences start-up and as General Counsel and Corporate Secretary of Analog Devices, a publicly traded semiconductor company. Larry holds a JD from Boston University School of Law and a BA in Political Science and Government from Tulane University.

Jessica Zeller
Vice President - Quality, Regulatory
& Public Affairs Counsel
Edwards Lifesciences

Jessica Zeller is Vice President - Quality, Regulatory, Environmental, and Public Affairs Counsel at Edwards Lifesciences based out of Irvine, CA. Edwards is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Jessica routinely counsels on global medical device regulatory compliance matters and quality systems concerns, including interacting with government regulators. She was previously FDA's inaugural ORA Ombudsman, focusing on problem-solving with respect to FDA's field offices, including inspections, imports, and other agency processes and procedures. Additionally, Jessica has served as the Deputy Director of Compliance and Enforcement for FDA's Center for Tobacco Products, as a litigation attorney in FDA's Office of Chief Counsel, and as the lead FDA lawyer for Procter & Gamble. Jessica holds a JD/MA (Bioethics) from University of Virginia and a BS (Biology) from Xavier University.

Covington Presenters

Wade Ackerman
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Wade Ackerman co-leads Covington's multidisciplinary Digital Health Initiative, which brings together the firm's considerable global resources to advise life sciences and technology clients harnessing the power of information technology and data to create new and cutting-edge

innovations to improve health and achieve better outcomes for patients. Wade advises companies and trade associations on complex and novel FDA regulatory issues that require coordinated legal, regulatory, and public policy strategies. Through more than 16 years of experience in private practice and positions within the FDA and on Capitol Hill, Wade has acquired unique insights into the evolving legal and regulatory landscape facing companies marketing FDA-regulated products.

John Balzano
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John Balzano represents companies and business associations on U.S. and China regulatory

and policy matters related to food, drugs, medical devices, cosmetics, and other regulated products. John has over a decade of experience with legal and regulatory issues related to China, particularly with regard to products regulated by the State Administration for Market Regulation, the National Medical Products Administration (NMPA), and other agriculture, animal and healthcare (including digital health) products and services. He assists clients with developing strategies to obtain pre-market approvals for these products in China, including clinical development, understanding relevant pricing and reimbursement policies, and reviewing distribution and promotional plans.

Sarah Cowlishaw
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Sarah is a partner in London and Dublin practicing in the areas of EU, UK and Irish life sciences law, and is a co-chair of Covington's multidisciplinary Digital Health Initiative. She advises clients on a broad range of life sciences matters, and supports innovative pharmaceutical, biotech, medical device, diagnostic and technology companies on regulatory, compliance, transactional, and legislative matters. Sarah has particular expertise in medical devices and diagnostics, and on advising on legal issues presented by digital health technologies, helping companies navigate regulatory frameworks while balancing challenges presented by the pace of technological change over legislative developments.

Scott Danzis
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Scott Danzis co-chairs Covington's Medical Device Industry Group and is a leading expert on the regulation of medical devices, diagnostics, and digital health. He regularly helps clients navigate their most complex regulatory challenges, including strategies for premarket review, postmarket compliance, and enforcement actions. Scott counsels many of the world's preeminent medical device companies on a range of matters, including advertising and promotion, recalls, quality system issues, medical device reporting, clinical and non-clinical testing, FDA inspections, and other regulatory matters.

Kristin Davenport
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Kristin Davenport advises medical device companies regarding premarket strategies and pathways, the premarket submission process, advertising and promotion, compliance and enforcement matters, and import/export issues. She has extensive experience with 510(k) premarket notifications, de novo petitions, premarket approval applications, investigational device exemptions, device modifications, 513(g) Requests for Information, MDR reporting, device recalls, and Part 806 reports. Kristin navigates issues that arise during the premarket review process, and has successfully represented device companies in administrative appeals.

Van Ellis
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Van Ellis advises biopharmaceutical, medical device, and digital health companies across the full range of transactions that arise during the life cycle of a product, including major collaborations, licensing arrangements, and a variety of commercial agreements. Van has more than 25 years of experience representing both multinational and early stage life sciences companies on matters ranging from billion-dollar global collaborations to daily commercial and operational matters. He also advises life sciences companies in connection with initial public offerings and mergers and acquisitions.

Ashden Fein
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Ashden Fein is a vice chair of the firm's global Cybersecurity practice. He advises clients on cybersecurity and national security matters, including crisis management and incident response, risk management and governance, government and internal investigations, and regulatory compliance. For cybersecurity matters, Ashden counsels clients on preparing for and responding to cyber-based attacks, assessing security controls and practices for the protection of data and systems, developing and implementing cybersecurity risk management and governance programs, and complying with federal and state regulatory requirements.

Pamela Forrest
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Pamela Forrest co-chairs Covington's Medical Device Industry Group. She has over 25 years of experience advising clients on a broad range of U.S. FDA regulatory issues, with a specific focus on medical device and digital health matters. She advises firms on the full life-cycle of FDA medical device requirements, including counseling them on market entry strategies, shepherding them through the FDA regulatory process, and helping them come into compliance with FDA's post-market controls. Pamela is also a recognized expert on FDA enforcement, and works closely with firms on responses to FDA enforcement actions, including inspectional observations and Warning Letters.

Megan Gates
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Megan Gates is a partner in Covington's Securities and Capital Markets practice and has been guiding publicly traded and late-stage private companies, primarily in the life sciences industry, through capital-raising transactions, SEC reporting compliance and corporate governance obligations, as well as strategic mergers and acquisitions' for over 25 years. Her clients benefit from the client-focused perspective she gained during a prior in-house counsel role with Thermo Electron Corporation, where she was responsible for securities offerings and compliance for the corporation and its 23 publicly traded subsidiaries. Megan frequently speaks at conferences on securities offerings, corporate governance, and compliance matters. She is also active in community organizations in Boston, including serving as a Board member or other leadership roles with the Pine Street Inn, the Boston Bar Foundation, and the Japan Society of Boston.

Geoff Hobart
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Geoffrey Hobart is a partner and focuses on the defense of companies and individuals who are under investigation by the government. Since returning to private practice in 2000, Geoff has specialized in the defense of pharmaceutical companies and their employees in investigations involving alleged violations of the False Claims Act, the Anti-Kickback Act, the Food Drug and Cosmetic Act, and the Medicaid Rebate Statute. Geof also has extensive experience

conducting internal investigations on behalf of a variety of companies.

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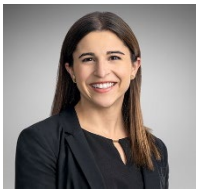
Christina Kuhn is special counsel in Covington's Medical Device Industry Group and multidisciplinary Digital Health Initiative. Her practice focuses on advising medical device, pharmaceutical, and biotech companies on a broad range of FDA regulatory strategy and compliance matters. She has experience with cutting-edge and complex medical technologies, including software and digital health products, oncology products, next-generation sequencing, diagnostics, and combination products.



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Amy Leiser assists medical device, laboratory, pharmaceutical, and biotechnology clients to operate within a complex, highly regulated area in a way that supports achieving their business goals while minimizing regulatory and litigation risks. With a focus on medical device, digital health, and diagnostic products and laboratory services, Amy regularly advises clients on a variety of state and federal regulatory, legislative, and compliance matters, as well as considerations for strategic engagement with the Food and Drug Administration (FDA).

Web Leslie
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Web Leslie represents and advises emerging and leading companies on a broad array of technology issues, including on cybersecurity, critical infrastructure, national security, investigations, and data privacy matters. Web provides strategic advice and counsel on cybersecurity preparedness, cyber and data security incidents, healthcare privacy and security, cross-border privacy law, and government investigations, and helps clients navigate complex policy matters related to cybersecurity, national security, and critical infrastructure protection.

Andrew Ment
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Andrew Ment's practice focuses on mergers and acquisitions and private equity transactions. Andrew's M&A experience includes public and private acquisitions and divestitures, leveraged buy-outs, "going private" transactions and joint ventures. Andrew also practices in the area of corporate finance, where his experience includes syndicated lending, royalty sales & financings, registered offerings, and private placements.

Weishi Li
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Weishi Li works with life sciences clients on cross-border transactions. Weishi leads the firm's China life sciences transaction practice, and previously served for five years as Managing Partner of the Shanghai office. Weishi has extensive experience assisting Western and Chinese life sciences companies in structuring and negotiating cross-border commercial, corporate, and partnering transactions involving China, including strategic collaborations, joint ventures, licensing, acquisitions, co-promotion, and distribution arrangements. As a registered U.S. patent attorney with a Ph.D. in microbiology and substantial food and drug regulatory experience, Weishi has a deep understanding of the complex issues confronting the industry and is well-versed in helping clients tackling such issues.